

Remarks

The October 9, 2003 Official Action has been carefully considered. In view of the present amendment, the Declaration of Paul Jarrett submitted herewith and these remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set in the October 9, 2003 Official Action. Accordingly, the initial due date for response was December 9, 2003. A petition for a three (3) month extension of the response period is presented with this submission under 37 C.F.R. §1.114, which is being filed before the expiration of the three (3) month extension period.

As another preliminary matter, it is noted that the Examiner is adhering to the requirements for restriction and election of species that were made final in the March 11, 2003 Official Action, for the reasons of record in the October 10, 2002 Official Action. Applicant's wish to make clear that the election of claims 3 and 53-58 in response to the aforementioned requirements for restriction and election of species is without prejudice to their right to file one or more divisional applications, as provided in 35 U.S.C. §121, directed to subject matter held finally withdrawn from consideration in this application.

In the October 9, 2003 Official Action, a number of rejections have been repeated and made final. Specifically,

claims 64 and 66 stand rejected as allegedly failing to satisfy the enablement requirement of 35 U.S.C. §112. The Examiner acknowledges that the specification is enabling for a method of identifying nucleotides that are homologous to SEQ ID Nos:1-4, but maintains the rejection of claims 64 and 66 based on the recitation "homologous variant...having about 70% or more sequence identity", in claim 64, and the recitation "nucleotides sequence which is a derivative", in claim 66.

Claims 54 and 56 are rejected as allegedly indefinite due to lack of antecedent basis for the recitation "wherein the agent has activity against insects of two or more orders selected from Lepidoptera; Coleoptera; Homoptera".

Claims 3, 53-56 and 63-66 are again rejected under 35 U.S.C. §102(b) as allegedly anticipated by, or in the alternative under 35 U.S.C. §103(a) as allegedly rendered obvious by the WO98/08388 (Jarrett et al.), considered in light of WO98/50427 (Ensign et al.).

The foregoing rejections constitute all of the grounds set forth in the October 9, 2003 Official Action for refusing the present application.

In accordance with the present amendment, claim 3 has been amended to provide appropriate antecedent basis for the recitation of the insect orders recited in claims 54 and 56. Support for this amendment of claim 3 is provided in the paragraph bridging pages 3-4 of the present specification.

Also in accordance with this amendment, claims 64 and

66 are cancelled, thus rendering moot the rejection of these claims based on alleged failure to comply with the enablement requirement of 35 U.S.C. §112. The cancellation of claims 64 and 66 in accordance with this amendment should not be construed as indicative of applicants' concurrence or acquiescence in the 35 U.S.C. §112 rejection of those claims, or otherwise as an abandonment of applicants' effort to secure patent protection on the subject matter of claims 64 and 66. To the contrary, applicants vigorously dispute the examiner's rejection of those claims. Such arguments as applicants have to advance and rebuttal, however, are being reserved for the filing of a possible continuing application including claims directed to subject matter withdrawn from consideration in this application.

A consequential amendment has been made in claim 65, as a result of the cancellation of claim 64.

No new matter has been introduced into this application by reason of any of the amendments presented herewith.

As a result of the foregoing amendment, the 35 U.S.C. §112 first paragraph rejection of claims 64 and 66 and the 35 U.S.C. §112 second paragraph rejection of claims 54 and 56 have been overcome. Thus, the only matters remaining to be addressed are the above-noted prior art rejections of claims 3, 53-56 and 63, and 65. For the reasons set forth below, these grounds of rejection are respectfully traversed.

The prior art rejections maintained by the examiner are fundamentally flawed and, therefore, cannot be maintained.

As a general rule, a rejection under 35 U.S.C. §102 is proper only if each and every element recited in the claim in question is described, either expressly or inherently, in a single prior art reference. Schering Corp. Geneva Pharmaceuticals, Inc. 67 USPQ 2nd 1664, 1668 (Fed. Cir. 2003). Applicants' claims call for a pesticidal agent from X. bovienii. There is no disclosure of this aspect of applicants' claims, either expressly or inherently, in W098/08388, which discloses a pesticidal toxin from X. nematophilus. The difference between X. bovienii and X. nematophilus is clearly illustrated in the dendogram of Fig. 1 of the present application. This difference, standing alone, negates a rejection under 35 U.S.C. §102. In re Arkley, 172 USPQ 524 (CC PA 1972).

Moreover, the claims recite that the pesticidal agent of the present invention has insecticidal activity against Lepidoptera, Coleoptera and Homoptera including species selected from Pieris brassicae, Plutella xylostella, Phaedon cochleariae and Myzus persicae. These recitations further serve to patentably distinguish the present invention over W098/08388, as the insect range affected by applicants' pesticidal agent is different from that of the toxin from the distinct bacterial species disclosed in W098/08388.

Although the Examiner asserts that such differences in the range of insect activity are inherent in the toxin disclosed in W098/08388, the Examiner has plainly failed to meet the burden of proof for establishing anticipation based on inherency. It

has long been required that when the PTO asserts that there is an express or implied teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears in the prior art. In re Rijckaert, 28 USPQ 2nd 1955, 1957 (Fed. Cir. 1993), citing In re Yates, 211 USPQ 1149, 1151 (CCPA 1981). The Examiner has unquestionably failed to satisfy this requirement. Rather, the Examiner assumes, without any factual support, that the pesticidal toxin described in WO98/08388 affects the same range of insects as that of applicants. There is certainly no disclosure in WO98/08388 that the pesticidal toxins described therein have any insecticidal activity against coleopteran pest species such as Phaedon and homopteran pest species such as Myzus. The Examiner is simply mistaken in stating, at page 6 of the March 11, 2003 Official Action, that WO98/08388 discloses pesticidal agents having the "same functional properties toward the members of same insect orders (i.e. Coleoptera, Homoptera or Lepidoptera) as recited in the instantly claimed invention". There is no mention whatsoever in WO98/08388 that the pesticidal agents described therein are effective against coleopteran or homopteran pest species.

Furthermore, The mere citation of WO98/50427 (Ensign et al.) in the October 9, 2003 Official Action, or any prior official action, does not constitute the indication required by In re Rijckaert, supra of a teaching or suggestion in the prior art that pesticidal agents from X. bovienii have insecticidal activity against at least one (1) insect species of an order

selected from the group consisting of Coleoptera, Homoptera or Lepidoptera, which insect species is selected from the group consisting of Pieris brassicae, Plutella xylostella, Phaedon cochleariae and Myzus persicae, as called for in applicants' claim 3. It is evident from the overall disclosure of W098/50427 that this reference fails to make up for the fundamental deficiencies in the disclosure of W098/08388, as noted herein. Thus, W098/50427 (i) fails to identify any of the Xenorhabdus strains disclosed therein as X. bovienii, (ii) fails to give any sequence information which can be compared with the presently claimed sequences, and (iii) fails to disclose the same insecticidal activities which are demonstrated for the present invention, e.g. at page 29 of the present specification. Silence in a reference is not a proper substitute for an adequate disclosure of facts from which a conclusion of unpatentability may justifiably follow. In re Burt, 148 USPQ 548 (CCPA 1966).

Having failed to meet the PTO's burden of proof, it is manifestly improper to require applicants to conduct a parallel test against each one of the insects that the prior art reference cites, which is essentially what the Examiner has done at page 4 of the October 9, 2003 Official Action. Nevertheless, in order to dispel any possible doubt regarding the substantial differences between the pesticidal agents of the present invention and those of W098/08388, there is submitted herewith a Declaration of Paul Jarrett, who is one of the co-inventors of the present invention. This declaration compares the pesticidal

agents of the present claims with toxins from X. nematophilus strains, including strains deposited as NCIMB 40887 and NCIMB 40886, which are disclosed in WO98/08388. The resulting data reflects the activity of the tested strains against a range of insects from four (4) different orders and shows a quite different range of activities. These data establish that the X. bovienii strains of the invention are surprisingly active against the aphid species Myzus persicae in comparison to the toxins from X. nematophilus, which did not shown activity under the conditions used in the experiment. Also, the X. bovienii strains tested were highly active against the coleopteran species Phaedon cochleariae, in contrast to the poor activity exhibited by the toxins from X. nematophilus. On the other hand, the two X. bovienii strains tested had little or no activity against the dipteran, mosquito pest species Aedes aegyptii, whereas the toxin from X. nematophilus under the same test conditions caused 100% larval mortality.

As stated in paragraph 7 of the Declaration of Paul Jarrett, is apparent from these experimental results that X. bovienii strains I73 and H31 have a very different spectrum of activity in comparison to the X. nematophilus strains tested. The declarant therefore concludes that the pesticidal agents of the present claims, which are obtained from X. bovienii strains I73 and H31, are different from those of the tested X. nematophilus strains. In other words, given that the overall range of activity varies between the pesticidal agent of the

present invention and that of W098/08388, it necessarily follows that the two (2) agents must be different.

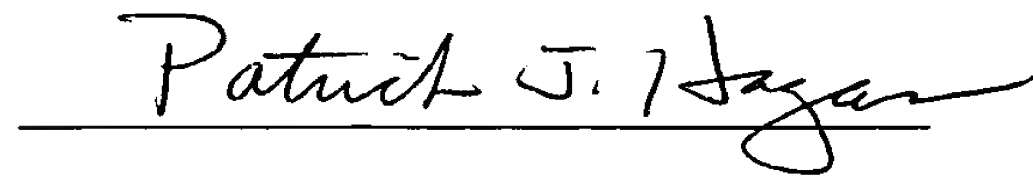
The declaration evidence presented herewith clearly refutes not only the above-noted anticipation rejection based on the theory of inherency, but the obviousness rejection, as well. The law is well-settled that evidence which shows that a composition of matter is unexpectedly superior in one of a spectrum of properties is sufficient to rebut a prima facie case of obviousness. Cf. In re Chupp, 2 USPQ 2nd 1437 (Fed. Cir. 1987) (copy attached); and In re Ackermann, 170 USPQ 340, 343, (CCPA 1971). See also Ex parte A, 17 USPQ 2nd 1716, 1719 (BPAI 1990) (Board of Appeals, citing In re Chupp, supra, rejected examiner's argument that to rebut evidence of obviousness of composition having antibacterial activity, it was necessary for composition to be unexpectedly different from prior art in its therapeutic effect against all bacteria). It is noted in this regard that the different range of insecticidal activities between the pesticidal agents of the present invention and those of W098/08388 could not reasonably have been predicted based on the prior art, and represents a beneficial and unexpected contribution to the art, where novel pesticidal agents having novel target ranges have great utility.

In view of the present amendment, the Declaration of Paul Jarrett submitted herewith and the foregoing remarks, it is respectfully requested that the rejection set forth in the October 9, 2003 Official Action be withdrawn and that this

application be passed to issue and such action is earnestly solicited.

Respectfully submitted,

DANN, DORFMAN, HERRELL and SKILLMAN

A handwritten signature in cursive script, reading "Patrick J. Hagan", is written over a horizontal line.

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PJH:cmb

Enclosures:

- Declaration of Paul Jarrett
- copy of In re Chupp, 2USPQ 2nd 1437 (Fed. Cir. 1987)